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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,393	08/28/2002	Antonius Helena Adolf Bom	0-1999.475 US	3834

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,393

Applicant(s)

BOM ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III (claims 11-14 and newly submitted claim 20) in the reply filed on June 1, 2004 is acknowledged. Applicant traverses on the ground that Group IV (claims 15-19) is drawn to pharmaceutical compositions used in the method of Group III. This is not found persuasive because, as discussed in the original restriction requirement, inventions which are thus related can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, it is the latter. The product, a pharmaceutical composition comprising a chemical chelator, can be used for drug delivery, as admitted by Applicant. See specification at page 5, lines 21-22.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-10 have been canceled. Claims 11, 12, 14, and 15 have been amended. Newly submitted claim 20 has been added. Claims 10-20 are pending. Claims 15-19 have been withdrawn as being drawn to a non-elected invention.

Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claim Rejections - 35 USC § 112

Claims 11-13 are again rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, as set forth in the previous Office action. Newly added claim 20 is included in this rejection.

Applicant's arguments filed June 1, 2004 have been fully considered but they are not persuasive.

Applicant states that the claims are now directed to a method of reversing NB without causing an increase in the level of acetylcholine. However, there is no evidence that the administration of a CD, as in DÉSIÉ, causes an increase in the level of acetylcholine, so the amended claim still encompasses the method disclosed by DÉSIÉ.

Applicant argues that the invention as now claimed is fully enabled and predictable. It appears that Applicant's reasoning for this statement is that the mechanism by which cyclodextrins inactivate some NB agents, such as the ones recited in claim 12, is different than that for the agents disclosed in DÉSIÉ. However, the fact that cyclodextrins deactivate NB agents by different mechanisms would support the original rejection in that the cyclodextrin interaction with these compounds is unpredictable.

To be clear, the examiner reiterates that the scope of enablement has two separate components: *Some* cyclodextrins (γ) are enabled for reversing the action of *some* NB agents (those recited in claim 12). The reason that claim 12 is included in the scope rejection is because not *all* cyclodextrins are enabled for this method, even if the independent claim were amended to

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include the recited agents. Newly added claim 20 is included because γ -cyclodextrin is not enabled for all NB agents that would be embraced by the independent claim.

Claim Rejections - 35 USC § 103

Claim 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DÉSIRÉ et al (Experientia, 1987).

Applicant's arguments filed June 1, 2004 have been fully considered but they are not persuasive.

Applicant first contends that in DÉSIRÉ the CD "is not acting as a chelator to form a complex, as in the method of the present invention." However, in the next paragraph, Applicant outlines the mechanistic steps set forth in DÉSIRÉ, step one being "a complex formation between cyclodextrin and the nerve agent." The examiner is perplexed by this contradiction and does not understand Applicant's point here.

Applicant further notes that DÉSIRÉ teaches that some NBs (sarin and soman) can be deactivated, but others cannot. The examiner agrees, and this was noted both in support for the scope of enablement rejection, *as well as* the discussion of allowable subject matter, but this is not germane to the present art rejection. It appears to be Applicant's position that the limitation "without causing an increase in the level of acetylcholine" distinguishes this invention from that of DÉSIRÉ. As noted above, the administration of CD does not cause an increase in the level of acetylcholine, so the instant method would still be obvious over the teaching of DÉSIRÉ.

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Double Patenting

Claims 11-14 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,670,340, as set forth in the previous Office action.

Applicant has indicated a willingness to submit a terminal disclaimer, if necessary, upon indication of allowability.

Allowable Subject Matter

DÉSIRÉ teaches as set forth above. The teaching is limited specifically to phosphonofluoridates. The reference does not teach or fairly suggest the instant method wherein the NB agents are those recited in claim 12. Claims 12, 14, and 20 appear to be free of the art but subject to other rejections set forth above. A claim limited to the recited NBs and γ -CD would appear to be fully enabled and free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
September 21, 2004


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600